



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,380	10/17/2001	Yasushi Kuraishi	45665/VGG/N74	7687
23363	7590	03/22/2004	EXAMINER	
CHRISTIE, PARKER & HALE, LLP 350 WEST COLORADO BOULEVARD SUITE 500 PASADENA, CA 91105			MOHAMED, ABDEL A	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/982,380

Applicant(s)

KURAISHI ET AL.

Examiner

Abdel A. Mohamed

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-9, 16 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-15 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

#### **ACKNOWLEDGMENT OF PRIORITY, IDS, RESPONSE TO THE RESTRICTION REQUIREMEN, STATUS OF THE APPLICATION AND CLAIMS**

1. Acknowledgement is made of Applicant's claim for priority based on Japanese Application Number 20001-44656 having a filing date of 2/21/01. Although, the certified copy of the Japanese Application Number 2001-44656 have not been perfected, receipt is acknowledged of papers submitted under U.S.C. § 119, which papers have been placed of record in the file. The information disclosure statement (IDS) and Form PTO-1449 filed 2/5/02 and the response to the restriction requirement filed 1/22/04 are acknowledged, entered and considered. Claims 1-18 are now pending in the application.

#### **ELECTION WITHOUT TRAVERSE**

2. Applicant's election of Group II, claims 10-18 in Paper No. 6 is acknowledged. Applicant has elected to prosecute the invention of Group II (claims 10-18) and species I without traverse and indicated that claims 10, 11, 12, 15 and 18 read on the elected species and requested that the examination be conducted on the elected claims. Contrary to Applicant's indication, claim 18 is drawn to Species III and claim 15 is drawn to Species I (See e.g., the election of species of the previous Office action). Thus, since the species are different for the reasons of record, claims 1-9 (Group I) and claim 18 (Species III) are withdrawn as non-elected invention. Hence, the Office action is directed to the merits of claims 10-15 and 17 as *per* elected invention.

### **OBJECTION TO THE SPECIFICATION, CLAIMS AND**

#### **ABSTRACT**

3. The specification, claims and abstract are objected in the recitation "45665/VGG/N74" at the front corner of each page of the specification, claims and abstract. Also, the abstract is objected in the recitation "VGG/vat" and "VAT IRV1048931.1-\* -10/15/01 4:31 PM" at the end corner of the abstract. Deletion of the above file locator from the disclosure of the specification, claims and abstract would obviate this objection.

### **OBJECTION TO THE ABSTRACT**

4. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

### **OBJECTION TO THE SPECIFICATION**

5. The disclosure is objected to because of the following informalities: On page 5, line 5, in the recitation "oninflammatory pruritus". It is believed to be typographical error. Amendment of the specification to recite "non-inflammatory pruritus" is suggested. Appropriate correction is required.

### **CLAIMS REJECTION-35 U.S.C. § 112<sup>2nd</sup> PARAGRAPH**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 1-15 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is indefinite and vague in the recitation "comprising the step of administering...." because it is not clear to what kind of administration the claim refers. If it is intended for oral or parenteral or intradermal or other means of administration, the mode or route of administration should be recited in the claim (e.g., administering orally or intravenously or subcutaneously, etc.) is suggested.

Claim 10 is indefinite in the recitation "one or more substances" because it is not clear how many more than one is more included or excluded 1 or 2 or 10<sup>3</sup>. Appropriate clarification is required.

Claim 10 recites the limitation "suffering the pruritus" in line 4. There is insufficient antecedent basis for this limitation in the claim because the preamble of claim 10 recites "noninflammatory pruritus" and it is not clear if the pruritus recited in line 4 of claim 10 refers to noninflammatory pruritus or inflammatory pruritus or both. Amendment of the claim to recite "suffering from the noninflammatory pruritus" or "suffering from said pruritus" is suggested.

Claim 15, line 4 is indefinite in the recitation "N $\omega$ -itro-arginine". It is believed to be typographical error. Amendment of the claim to recite "N $\omega$ -nitro-arginine" is suggested.

#### **CLAIMS REJECTION-35 U.S.C. 102(b)/103(a)**

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10-15 and 17 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over any one of the following references of Tsukumo et al. (The Japanese Journal of Pharmacology, Vol. 114 [Suppl. 1] pp. 17-P-21P, 1999), Shinkado et al. (The Japanese Journal of Pharmacology, Vol. 85 [Suppl. 1] P625-P628, 2001) and Hideki et al. (International Journal of Dermatology Vol. 34, No. 4, pp. 292-295, 1995).

Each one of the references cited above treat non-inflammatory pruritus (atopic pruritus) in a patient by administering one or more substances having an activity of inhibiting an effect of nitric oxide (NO), wherein the test substance administered is N $\omega$ -nitro-L-arginine methyl ester (L-NAME) or N $\omega$ -nitro-L-arginine (NLA) and as control D-NAME. The L-NAME and NLA resulted in decreasing the number of scratching (i.e., the composition is effective to pruritus-itching or scratching) indicating the inhibition of L-NAME is the result of inhibition of nitric oxide synthase (NOS), because the scratching action was only inhibited by LNAME or NLA and was not inhibited by the subcutaneous

administration of equivalent amount of D-NAME, which was used as control (See e.g., abstract, Figures 2 and 3 of Tsukumo et al.; P-628 of Shinkado et al.; and page 294, right column of Hideki et al., respectively). Also, see each cited document in its entirety. Because the claims are drawn to a method of treating non-inflammatory pruritus in a patient by administering one or more substances having an activity of inhibiting an effect of NO, the claims are anticipated and/or rendered obvious over the cited art.

Note: the Examiner is not in a position to establish the mechanism of action for a therapeutic compound, i.e., use of the therapeutic compound in a method of treating a patient; hence, the burden is on the Applicant to show the differences, if any. In any event the discovery of the mechanism for the action of **a therapeutic compound** in a treatment method does not render patentability to the **same therapeutic compound** used in the same method.

#### CITATION OF RELEVANT PRIOR ART

8. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure: Lerner et al. (U.S. Patent No. 6,160,021) teach a method of treating a subject for unwanted epidermal or dermal condition comprising administering to the subject a hemoglobin compound to modulate the level of NO in the skin.

Murrell (U.S. Patent No. 6,190,704) discloses methods and composition for promoting healing of damaged tissue that result in an increased level of NO in the vicinity of the damaged tissue and the inhibition of unwanted wound healing by inhibiting the activity of NO in the tissue.




### CONCLUSION AND FUTURE CORRESPONDENCE


9. Claims 1-15 and 17 are rejected and claims 1-9, 16 and 18 are withdrawn as non-elected invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed number is (571) 272-0955. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951. The appropriate fax phone number for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 305-7401 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196

 Mohamed/AAM  
March 16, 2004

  
ROBERT A. WAX  
PRIMARY EXAMINER